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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,922	05/10/2001	Toshihiro Kuroita	10089/14	5846
26646	7590	07/11/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,922	KUROITA ET AL.	
	Examiner Richard G. Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12,25-28,30,32 and 36-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12,25-28,30,32 and 36-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Applicant's amendment of claims 4 and 6-12 and the cancellation of claims 33, 34 and the addition of new claim 42, in the paper of 4/20/2006, is acknowledged. Claims 1-12, 25-28, 30, 32 and 36-42 are still at issue and are present for examination. Applicants' arguments filed on 4/20/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 1, 2, 4 and 42 are objected to because of the following informalities:

Claims 1, 2, 4 and 42 each contain amino acid sequences which should have an accompanying sequence identifier (i.e. SEQ ID NO:).

Newly added claim 42 is a duplicate of claim 1. See also applicant's comments in response to the previous 112 second paragraph rejection, which support this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 25-28, 30, 32 and 36-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to the claims previously. In response to this rejection applicants have amended claims 4 and 6-12 and cancelled claims 33 and 34 and added new claim 42 and traverse the rejection as it applies to the newly amended claims. Claim 42 is included in the rejection for the reasons previously stated for claims 1-3, 25-28, 30 and 32, 33 and 35-41.

Applicants submit that they disagree that the specification only provides the representative species from *Pyrococcus furiosus*, *Pyrococcus kodakaraensis KOD1* or *Thermococcus litoralis* on the basis that applicants disclose on page 18, line 22 to page 19, line 11 that the modified thermostable DNA polymerase has the DX₁EX₂X₃X₄H sequence. Applicants submit that the specification states that there is no restriction on the origin of the thermostable DNA polymerase having the DX₁EX₂X₃X₄H sequence, and thus there is descriptive support for the *Pyrococcus* or *Thermococcus* genus as the origin.

Applicants further submit that the designation of "(*Pyrococcus*)" and "(*Thermococcus*)" in Figure 1 provide additional descriptive support for the claimed subgenera. This argument is also acknowledged but not found persuasive for the

reasons previously made of record, that while applicants have not adequately described the claimed sub-genus of any *Pyrococcus* or *Thermococcus* species.

Applicants additionally submit that various references cited in the attached IDS describe additional *Pyrococcus* and *Thermococcus* species and that the crystal structures of DNA polymerases from the *Pyrococcus* and *Thermococcus* genera were shown to be essentially identical.

Applicants further submit a chart showing the homology of the amino acid sequences of two species of Pfu and KOD1 showing a high degree of homology, in support of applicant's position that applicants have met the written description requirement.

Applicants complete argument is acknowledged, however, not found persuasive because the applicants disclosure of the three species of *Pyrococcus furiosus*, *Pyrococcus kodakaraensis KOD1* and *Thermococcus litoralis* in combination with the disclosure that the modified thermostable DNA polymerase has the DX₁EX₂X₃X₄H sequence is insufficient to adequately describe the subgenus directed to any *Pyrococcus* or *Thermococcus* species . The disclosure of two and one species, respectively is insufficient to describe the hundreds of *Pyrococcus* and *Thermococcus* species that exist.

Additionally arguments supporting the structural similarity of certain species from the *Pyrococcus* and *Thermococcus* genera is not helpful in the description of these genera at the time of invention. Thus the rejection of record remains for the reasons previously stated and repeated herein.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-3, 25-28, 30 and 32, 33 and 35-41 are further rejected under this statute on the basis that the modification of those DNA polymerases "obtained from ***Pyrococcus* or *Thermococcus* genus...**" are not supported by the specification at the time of filing and thus considered new matter (See also above 112 second paragraph rejection). Specifically, the genus of polymerases directed to any modified polymerase from ***Pyrococcus* or *Thermococcus* genus** is not supported by the specification at the time of filing.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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